

Notice of Allowability

Application No.

09/763,329

Examiner

Ashwin Mehta

Applicant(s)

MESSING ET AL.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 15 July 2004.
2. ☒ The allowed claim(s) is/are 11,13,14,16,17,22,23 and 25-29.
3. ☒ The drawings filed on 15 July 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 7192004
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 15, 2004 has been entered.
2. The rejections of claims 11, 13, 14, 17, 22-27, 29, and 30 under 35 U.S.C. 112, 1st paragraph, are withdrawn in light of the claim amendments.
3. The rejection of claims 11, 13, 14, 16, 17, and 22-24 under 35 U.S.C. 112, 1st paragraph, is withdrawn in light of Applicants' arguments.
4. The rejection of claims 11, 17, 22-25, 29, and 30 under 35 U.S.C. 103(a) is withdrawn in light of the claim amendments.

Examiner's Amendment

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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Authorization for this examiner's amendment was given in a telephone interview with Scott Scioli on September 15, 2004. The application has been amended as follows:

In the claims:

11. A method of making [high methionine] corn seeds that produce increased amounts [saturation levels] of 10 kDa zein and increased methionine content [in a plant with the *dzrl* negative dominant allelic composition], comprising the steps of:
 - a) transforming cells of a *dzrl* negative dominant allelic corn plant with a vector comprising a chimeric gene encoding a maize 10 kDa zein, wherein the chimeric gene comprises a maize 10 kDa zein coding region operably linked at its 5' end to a promoter, and at its 3' end to a heterologous 3' UTR, wherein the product of the *dzrl* negative dominant allele negatively regulates expression of an endogenous maize 10 kDa zein gene, comprising its native 3' UTR, in said corn plant;
 - b) regenerating from the transformed cells a fertile transgenic corn plant expressing the chimeric gene; and
 - c) producing seeds comprising the *dzrl* negative dominant allele from the plant, wherein the seeds express the chimeric gene and produce increased amounts [, thereby producing saturation levels] of the 10 kDa zein, thereby increasing methionine content of said seed [in a plant with the *dzrl* negative dominant allelic composition].
22. The method of claim 11, further comprising the step of breeding the fertile transgenic corn plant with another corn plant to produce [high methionine seed-producing] progeny corn

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plants that produce seeds with increased methionine content and comprising said *dzt1* negative dominant allele and said chimeric gene.

23. A [high methionine seed-producing] progeny corn plant that produces seed with increased methionine content, said progeny corn plant produced by the method of claim 22.

25. A fertile, transgenic corn plant that produces [high methionine] corn seeds with increased methionine content [in the presence of the *dzt1* negative dominant allelic composition of the seed], wherein said plant contains a *dzt1* negative dominant allele in its genome, and [transformed with a vector comprising] a chimeric gene encoding a maize 10 kDa zein, wherein the chimeric gene comprises a maize 10 kDa zein coding region operably linked at its 5' end to a promoter, and at its 3' end to a heterologous 3' UTR, wherein said seeds comprise the *dzt1* negative dominant allele and the chimeric gene.

29. A [high methionine seed-producing] progeny corn plant that produces seed with increased methionine content, said plant produced by breeding the fertile transgenic corn plant of claim 25 with another corn plant, wherein said progeny corn plant comprises said *dzt1* negative dominant allele and said chimeric gene.

The title was amended as follows:

METHOD [COMPOSITIONS AND METHODS] FOR PRODUCING HIGH METHIONINE [HIGH-LEVEL SEED-SPECIFIC GENE EXPRESSION IN] CORN SEEDS

6. Claims 11, 13, 14, 16, 17, 22, 23, and 25-29 are allowed.

7. The following is an examiner's statement of reasons for allowance: The *dzr1* allele in corn plants regulates the 10 kDa zein gene in a dominant negative manner. Applicants have determined that the *dzr1* allele inhibits accumulation of mRNA coding for the 10 kDa zein protein by interacting with the 3'UTR of the zein mRNA. Applicants have devised method to increase the amount of 10 kDa zein in corn seeds by introducing into corn plants comprising the *dzr1* negative dominant allele, a chimeric gene comprising the coding region for the 10 kDa zein operably linked to a heterologous 3' UTR. As the 10 kDa zein protein is rich in methionine, increasing the amount of the 10 kDa zein in corn seeds also results in increased methionine content. The prior art teaches a method for co-expressing the 15 kDa zein and the 10 kDa zein in vegetative tissues of transgenic plants, such that they form protein bodies (Bragga et al., U.S. Patent No. 5,990,384). The prior art also teaches that the *dzr1* locus in corn negatively regulates 10 kDa zein accumulation (Chauduri et al., Mol. Gen., Genet., 1995, Vol. 246, pages 707-715). However, the prior art does not teach or fairly suggest that the *dzr1* locus inhibits 10 kDa mRNA accumulation via the 3' UTR of the 10 kDa zein mRNA, or that expression of the 10 kDa zein can be increased in corn seeds comprising the *dzr1* allele by introducing a chimeric 10 kDa zein gene comprising a heterologous 3' UTR.

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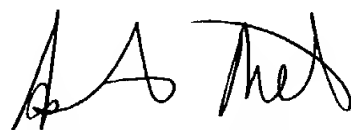
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

September 15, 2004



Ashwin D. Mehta, Ph.D.
Primary Examiner
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